

I. AMENDMENT

Amendments to the Claims:

1. (Currently amended) A liquid combination vaccine comprising antigens for protecting a subject against at least diphtheria ('D'), tetanus ('T'), pertussis ('P') and *Haemophilus influenzae* type b ('Hib'), wherein: (a) the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide; (b) the concentration of the Hib conjugate in the vaccine is $<15 \mu\text{g/ml}$; and (c) ~~the Hib conjugate has never been lyophilised~~ the vaccine comprises an aluminium phosphate adjuvant; (d) no more than 15% by weight of the Hib conjugate in the vaccine is adsorbed to aluminium phosphate; (e) the vaccine does not contain an aluminium hydroxide adjuvant; and (f) the vaccine does not contain an aluminium potassium sulphate adjuvant.

2. (Currently amended) A vial having a piercable seal and containing a liquid combination vaccine, which combination vaccine comprises antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H. influenzae* type b ('Hib'), wherein the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide, and wherein: (a) the concentration of the Hib conjugate in the vaccine is $<15 \mu\text{g/ml}$, and (b) the vial's piercable seal has not been pierced; (c) the vaccine comprises an aluminium phosphate adjuvant; (d) no more than 15% by weight of the Hib conjugate in the vaccine is adsorbed to aluminium phosphate; (e) the vaccine does not contain an aluminium hydroxide adjuvant; and (f) the vaccine does not contain an aluminium potassium sulphate adjuvant.

3. (Currently amended) A hermetically-sealed container containing a liquid combination vaccine comprising antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H. influenzae* type b ('Hib'), wherein (a) the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide; (b) ~~and wherein~~ the concentration of the Hib conjugate in the vaccine is $<15 \mu\text{g/ml}$; (c) the vaccine comprises an aluminium phosphate adjuvant; (d) no more than 15% by weight of the Hib conjugate in the vaccine is adsorbed to aluminium phosphate; (e) the vaccine does not contain an

aluminium hydroxide adjuvant; and (f) the vaccine does not contain an aluminium potassium sulphate adjuvant.

4. (Currently amended) A process for preparing a liquid combination vaccine comprising antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H. influenzae* type b ('Hib'), wherein (a) the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide; (b), and the concentration of Hib conjugate in the vaccine is <15 µg/ml; (c) the vaccine comprises an aluminium phosphate adjuvant; (d) no more than 15% by weight of the Hib conjugate in the vaccine is adsorbed to aluminium phosphate; (e) the vaccine does not contain an aluminium hydroxide adjuvant; and (f) the vaccine does not contain an aluminium potassium sulphate adjuvant,

characterised in that the process does not include one or both of the following steps: (i) a step of lyophilisation of the Hib conjugate antigen; (ii) a step of packaging the diphtheria, tetanus and pertussis antigens in admixed form separately from the Hib conjugate antigen.

5. (Currently amended) A process for inserting a liquid combination vaccine into a container, wherein: (a) the vaccine that comprises antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H. influenzae* type b ('Hib'); (b) the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide; ~~and~~ (c) the concentration of the Hib conjugate in the vaccine is <15 µg/ml; (d) the vaccine comprises an aluminium phosphate adjuvant; (e) no more than 15% by weight of the Hib conjugate in the vaccine is adsorbed to aluminium phosphate; (f) the vaccine does not contain an aluminium hydroxide adjuvant; and (g) the vaccine does not contain an aluminium potassium sulphate adjuvant.

6. (Currently amended) A process for attaching a label to a container, wherein: (a) the container contains a liquid combination vaccine that comprises antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H. influenzae* type b ('Hib'); (b) the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide; ~~and~~ (c) the concentration of the Hib conjugate in the vaccine is <15 µg/ml;

(d) the vaccine comprises an aluminium phosphate adjuvant; (e) no more than 15% by weight of the Hib conjugate in the vaccine is adsorbed to aluminium phosphate; (f) the vaccine does not contain an aluminium hydroxide adjuvant; and (g) the vaccine does not contain an aluminium potassium sulphate adjuvant; and (h) the process comprises a step of attaching a label to a container.

7. (Currently amended) A process for inserting a combination liquid vaccine into a container and then extracting the vaccine from the container, wherein: (a) the vaccine comprises antigens for protecting a subject against at least diphtheria, tetanus, pertussis and *H. influenzae* type b ('Hib'); (b) the antigen for protecting against Hib is a conjugate of a Hib capsular saccharide; and (c) the concentration of the Hib conjugate in the vaccine is <15 µg/ml; (d) the vaccine comprises an aluminium phosphate adjuvant; (e) no more than 15% by weight of the Hib conjugate in the vaccine is adsorbed to aluminium phosphate; (f) the vaccine does not contain an aluminium hydroxide adjuvant; and (g) the vaccine does not contain an aluminium potassium sulphate adjuvant.

8-10. (Canceled)

11. (Original) The vaccine, vial, container or process of any preceding claim, where the diphtheria antigen comprises a diphtheria toxoid, the tetanus antigen comprises a tetanus toxoid, and the pertussis antigen comprises a cellular pertussis component.

12. (Original) The vaccine, vial, container or process of any preceding claim, where the conjugate comprises a CRM₁₉₇ carrier, a tetanus toxoid carrier or an outer membrane complex of *N. meningitidis* carrier.

13. (Original) The vaccine, vial, container or process of any preceding claim, where the conjugate comprises an oligosaccharide fragment of the Hib polyribosylribitol phosphate.

14. (Canceled)

15. (Canceled)
16. (Withdrawn) A method for raising an antibody response in a mammal, comprising administering the vaccine of any preceding claim to the mammal.
17. (New) The vaccine, vial, container or process of any preceding claim, wherein at most 5% of the Hib conjugate in the vaccine is adsorbed to aluminium phosphate.
18. (New) The vaccine of claim 17, wherein at most 1% of the Hib conjugate in the vaccine is adsorbed to aluminium phosphate.
19. (New) The vaccine of claim 11, wherein the diphtheria toxoid and the tetanus toxoid are adsorbed onto aluminium phosphate.
20. (New) The vaccine, vial, container or process of any preceding claim, wherein the conjugate has a saccharide:protein ratio (w/w) of between 1:5 and 5:1.
21. (Withdrawn -- New) The method of claim 16, wherein administration of the vaccine results in an anti-PRP antibody concentration of $\geq 0.15 \mu\text{g/ml}$.